

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION

MONICA L. BALL,

Plaintiff,

V.

Case No. 3:13-cv-168

TAKEDA PHARMACEUTICALS

AMERICA, INC., et al.,

Defendants.

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR
RELIEF UNDER F.R.C.P. 60(b) FROM COURT'S ORDER GRANTING DEFENDANTS'
MOTION TO COMPEL AND ATTORNEY FEES**

Plaintiff respectfully request that the Court to grant her relief under F.R.C.P. 60(b).

The court granted the Defendants motion to compel and attorney fees. (See Exhibit A). Plaintiff is asking for a Rule 60(b) ruling. As set forth in the attached Declaration of Jerrod M. Smith, plaintiff's counsel filed an opposition to the Defendants' memorandum in support of the motion to compel, and now the Plaintiff is requesting relief under F.R.C.P. 60(b) due to the Defendants' did not have clean hands in regards to the issues of discovery, and the fact that the Plaintiff was seeking in good faith to resolve the issues of discovery. Further, the Defendants failed to answer admissions regarding material issues concerning the FDA and Dexilant in the use safe treatment of GERD, which Plaintiff Ball had, for which Plaintiff was given 60mg, when the FDA only approve 30mg tablet for the treatment of GERD.

FACTUAL BACKGROUND NOT PROVIDED TO THE COURT

On the date of June 26, 2013 after sending the release forms for medical records to the attention of the Defendants to get the records themselves, as the Defendants had requested at the 26(f) hearing before the court. Further, on the date of June 26, 2013 after having phone conversations, and e-mail discussions regarding the discovery issues, the Plaintiff counsel contacted the Defendants in regards to the failure to follow the court's order regarding the settlement conference.

On the date of June 26, 2013 the Plaintiff's attorney contacted the Defense counsel and asked him to comply with the Court's order regarding the dates that he was available for the settlement conference. Plaintiff's counsel asked for the Defense counsel to respond with the dates on that same that he would be available so that Plaintiff's counsel could call the magistrates office to set the date for the settlement conference.

The dates of October 15, 2pm; October 21, 2pm; October 22, 2pm, October 23, 2pm; October 24, 2pm, October 25, 2pm, November 4, 2pm, November 5, 2pm, and November 6, 2pm. See Exhibit B.

However, the Defense counsel did not respond on June 26, 2013 with the dates that he would be available, and never provided a response so that we could comply with the court's order.

In the same e-mail, Plaintiff's counsel stated that he wanted to talk to Defense counsel in regards to his issues with the insufficient answers to discovery that the Defendants had given to the Plaintiff. At that time Plaintiff wanted the admissions, and the documents as well as the answers to interrogatories to the experts he was speaking to in regards to the matter.

When the Defense counsel did not respond in regards to being available for the settlement conference, and when Defense counsel did not respond to having a phone conversation

concerning the issues of discovery that the Plaintiff had as well as the settlement conference request obtain from the magistrates clerk, the Plaintiff's counsel did not respond. See Exhibit C which shows the time spent on the phone of nine minutes with the magistrate's clerk to get dates to send to Defendants on June 26, 2013 at 11:31am. The number that was connected to Plaintiff's counsel's phone was that of (804) 916-2890. Defense counsel did not respond on that day, and Defense counsel never responded to Plaintiff's request to comply with the Court's order.

Then the next day Plaintiff's counsel was taken aback when the Defense counsel stated that they were going to do a motion to compel.

Plaintiff had discussions with the Defendants of the following days where the only issues were only the production of documents which the plaintiff submitted release forms to the Defendants so they could get the records. In addition, the Plaintiff sent the smaller files to the Defendants via e-mail. Then finally, if the Defendants could not wait, the Plaintiff offered the Defendants the ability to come to the Plaintiff's office to copy the materials.

Plaintiff had worked with the Defendants on the telephone on the dates of April 17, 2013; May 8, 2013; May 29, 2013. In addition, the Plaintiff emailed the Defendants on matters on the dates of June 26, 2013; June 25, June 19, 2013; June 13, 2013; June 12, 2013; June 5, 2013; and May 31, 2013. The Plaintiff operated in good faith in these negotiations.

But, when the Plaintiff mentioned his client's issues with the Defendants' failure to answer admissions, interrogatories, and production of documents the Defendants did not respond.

Further, when the Plaintiff tried to get the Defendants to comply with the Court's Order to set a settlement conference, the Defendants did not respond once again.

Plaintiff states that this was done in bad faith, since Plaintiff's counsel asked for the call to discuss the issue of complying with the court's order to have the settlement conference, and the Plaintiff also asked for the call to discuss issues of discovery so that it would be a two sided conversation since the Defendants answers were significantly more incomplete than the Plaintiff could have ever been.

So the proof that the Plaintiff requested a call from the Defendants to discuss the issues, and the Defendant failed to make the call when it was requested, and then they went forward with a motion to compel is contrary to the requirements of obtaining a motion to compel.

Further, Plaintiff had sent all the files that he could in the email system that he has, all of the other medical records were in big files and Plaintiff's counsel could not send them via the email because they were too large. Therefore, Plaintiff's counsel sent signed release forms to Defendants so that they could purchase the medical records themselves. These medical release forms had been sent and received by Defendants when they did the motion to compel.

See Exhibit B in regards to the emails sent to the Defendants. Therefore, the Plaintiff did not withhold and medical information from the Defendants. In addition, Exhibit B shows that the Plaintiff's made the records available under the Federal Rules of Civil procedure to the Defendants at any time they would request to see the documents.

It is clear that the Defendants failed to make the call to the Plaintiffs as requested to have a two way discussion in regards to the issues that the Plaintiff had with discovery, and to comply with the Court's order to setup to contact the magistrate.

Plaintiff counsel spoke with Defense counsel about the discovery as well as complying with the Court's order, but the Defense counsel refused to comply with the Court's order. This was attempted on the date of May 17, 2012 at 9:24am.

Further, the Defendants did not supply any of the documents that the Plaintiff requested concerning material issues such as the issue of misleading the FDA in regards to the Dexilant product that was waged by former employee and the United States Government. Further, the Defendants did not supply the answers to interrogatories, or admission as the court now knows.

Further, Plaintiff asked for the complete information in discovery, and the Defendants have failed in providing Admissions, and answers to interrogatives and have failed to provide the demand for documents.

Plaintiff uncovered the information and believe it is timely in requesting of this court to have the order dismissing the fraud, and expressed warranties be over turned and the Plaintiff allowed to amend the complaint to include the present claims, as well as the fraud and expressed warranties. The fact that the Defendants did not list Stevens Johnson Syndrome in the expressed warranties listed in the 2010 Physicians' Desk Reference, nor in the 2011 Physicians' desk reference is significant.

Plaintiff's responses to discovery were replete with the fact that the Plaintiff needed expert opinions to assist in the answering of the question correctly. This brings us back full circle in regards to having our experts paid and on board. The Defendant's delays in admissions and other discovery request do not help in cutting down the cost of experts.

The fact that our experts have our clients information, has nothing to do with whether we have been able to pay them in full at this time. Defendants' delays do not help in this regard either.

The Defendants failed to answer these simple admissions which would aid her non-medical and her medical experts. Defendant were specifically asked for the information related to the whistleblower claims that the United States brought against them, and the Defendants have refused to provide the information related to the Dexilant 60mg versus the 30mg approval of the FDA to treat GERD.

The Defendants are presenting a fluid response to the Plaintiff's request, and are not proving solid answers.

For instance, in the issues of fertility their answers to this Court as well as to the Plaintiff are evasive and fluid, and in this type of atomphere the need of the expert opinion will be just as fluid as well in regards to liability and the injuries that were incurred by the Plaintiff.

Defense counsel stood before this Court and stated that the Plaintiff's allegations which included fraud were only conclusory and and speculative allegations all the while knowing that his client had been sued on the very issues of fraud and misrepresentation to the FDA.

MR. WRIGHT: Your Honor.

Well, Your Honor, with all the redundancy in the complaint, and the conclusory allegations and speculative allegations, what plaintiff, I think, is trying to allege is simply a failure to warn claim. That is what it boils down to. We know that when the case was, the earlier case was filed, the focus was on Steven-Johnson, Your Honor.

THE COURT: Well, injuries are fluid.

MR. WRIGHT: YES.

Mr. Wright made these allegations against the complaint that Plaintiff submitted with the issues of fraud, yet knowing that the Whistleblower claim was being litigated by the United States which had issues with making misrepresentations to the FDA about Dexilant, and misinforming the physicians about the dosage to treat GERD which Plaintiff Monica Ball had before she incurred her injuries.

THE COURT: Are Dexilant research studies on the side effects of Dexilant, or sorry, Takeda's research studies on the side effects of Dexilant, are they available to the public?

MR. WRIGHT: They are – I do not believe they are available to the public. They are provided to the FDA. Perhaps with a FOIA request you could get them from the FDA.

THE COURT: But not generally available. I couldn't go to the library and look at them.

MR. WRIGHT: That is right. They are described in summary form, as you know, in the warning materials. (See page Transcript April 16, 2013, page 8 lns 8-19).

It has been discovered that while the Defendant were purporting to this court that fraud was not applicable, they had been accused of fraud by the United States Government concerning the misrepresentation of Dexilant for the treatment of GERD in the form of 60mg, for which the FDA had only approved 30mg for GERD treatment. Further, the whistleblower also stated that Defendant Takeda made misrepresentations to the FDA and physicians concerning the drug Dexilant.

Defendants counsel made this statement to the court knowing that they had litigation on the issue of the Defendants misrepresenting to the FDA as well as physicians the issue of 30mg

of Dexilant being approved by the FDA, and the 60mg being advertised to doctors as being safe to treat the Plaintiff GERD.

The issue of fraud is what the Defense counsel tried to stir the court from, and Defense counsel only wanted the Court to concentrate on the issue of the failure to warn. When the Defense counsel directed the court attention away from the issues of fraud, and the material breach of an expressed warranty, the Defense counsel knew of the allegations concerning the misrepresentations to the FDA and physicians by Defendants Takeda et al.

This was known at the time the Defendant's counsel made these representations to the Court, and purposely narrowed the argument to just that of failure to warn for the most part.

Therefore, the Defense counsel using a statement made by the Plaintiff's counsel before the fluid information came into the Plaintiff's knowledge, only is applicable if litigation is found to hold a pattern in a vacuum, or in tunnel visions. However, when Defense counsel knew or should have known of the allegations of the Whistleblowers concerning the misrepresentations regarding Dexilant, it gives the court another issue to consider regarding the fluid litigation in these convoluted cases.

Plaintiff's counsel did not find the documents until after the Court in the whistleblower case removed the protective order.

Further, the Defendants knew that issue of fraud were encompassed in the present case in the hearing of April 26, 2013.

Facts Support of Granting Plaintiff's Rule 60(b) Motion

The entire facts surrounding the issues give rise to the Court have sufficient reasons to overturn the dismissal of the fraud and the expressed warranties and allow the Plaintiff to submit a new motion to Amend the complaint, and memorandum.

Defendants knew when they asked this court to dismiss the expressed warranties, and fraud that they did not have the issue of Stevens Johnson in the Physicians' Desk Reference. As this court knows fraud is not only actual fraud, but it is also based upon negligence as well. It is a fact that the Physicians' Desk Reference does not have warnings to Physicians concerning Stevens Johnson Syndrome in the 2010 and the 2011 publications of the Physicians' Desk Reference.

Further, the Defendants had in this knowledge as well as the allegations of misrepresentation in the whistleblower case in their possession and control. The Defendants and their counsel also knew of the information that they had advertised and sold Dexilant to cure GERD using 60mg, when the FDA had only approved 30mg tablets in the treatment of the disease of GERD. Plaintiff Monica Ball suffered from GERD, and she took an overabundance of 60mg to treat GERD, when the FDA had only approve 30mg for her needed treatment. Plaintiff Monica Ball was given 60mg samples for almost 30 days, and she took this medication as prescribed. Lab test show that extreme or prolong use of the ingredients in Dexilant could cause deformities in uterus in lab experiments. Defendants withheld the information that the lawsuit was active, and failed to admit questions about the misrepresentation, and also failed to provide documents and sufficient answers to interrogatories.

Such withholding of information from this Court as well as the Plaintiff is enough information to suffice as a basis to set aside the Court's Order granting the Defendants' motion to dismiss the issue of fraud, and the count of expressed warranties under F.R.C.P. 60(b).

ARGUMENT

1. Basis of Rule 60

F.R.C.P. 60(b) sets forth the circumstances in which a court may relieve a party from what would otherwise be a final judgment. Those circumstances include "(1) mistake, inadvertence, surprise, or excusable neglect; [...] or (6) any other reason that justifies relief." *Id.*

Motions for reconsiderations are not vehicles for relitigating old issues, or motions for "initial consideration" unless the arguments or evidence were not available earlier. *See Sigsworth v. City of Aurora*, 487 F.3d 506, 512 (7th Cir. 2007); *National Ecological Found. v. Alexander*, 496 F.3d 466, 477 (6th Cir. 2007).

The Defendants had in their possession, but the Plaintiff did not have in her possession the information concerning the allegations of misrepresentations to the FDA and physicians regarding the Dexilant 60mg versus the 30mg dosages.

(b) Mistakes; Inadvertence; Excusable Neglect; Newly Discovered Evidence; Fraud, etc.

On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b);

(3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct

of an adverse party;

(4) the judgment is void;

(5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or

(6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken.

A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court to entertain an independent action to relieve a party from a judgment, order, or proceeding, or to grant relief to a defendant not actually personally notified as provided in Title 28, U.S.C. § 1655, or to set aside a judgment for fraud upon the court. Writs of coram nobis, coram vobis, audita querela, and bills of review and bills in the nature of a bill of review, are abolished, and the procedure for obtaining any relief from a judgment shall be by motion as prescribed in these rules or by an independent action.

2. Grounds for motion

A misrepresentation to this court, or the idea of trying to move the court from an issue that the Defendants knew was at issue, is sufficient enough grounds for the court to reverse its decision to dismiss the counts of fraud and breach of expressed warranty.

Relief for the Plaintiff is necessary to ensure that the Plaintiff do not suffer because opposing counsel directed the Court from the issues of fraud and expressed warranty found in the FDA, and information to Physicians given to Plaintiffs along with the expressed warranty of the prescription, and the information on the dosage and treatment.

Plaintiff respectfully asks for a finding that the phrasing of Rule 60(b) “free[s] courts to do justice in cases in which the circumstances generally measure up to one or more itemized grounds.”)

CONCLUSION

Plaintiffs respectfully request that the Court GRANTS plaintiffs’ motion for relief under F.R.C.P. 60(b) FROM COURT’S ORDER GRANTING DEFENDANTS’ MOTION TO COMPEL AND ATTORNEY FEES and hereby reversed the order for the Plaintiff and Plaintiff’s counsel to answer discovery until expert witnesses are fully paid retainer fees, and the Court also reverses the order granting attorney fees to the Defendants by the Plaintiff and Plaintiff’s counsel.

July 27, 2013

Respectfully submitted,

By: /s/
Jerrold M. Smith, Va. Bar No. 66279
JERROD MYRON SMITH & ASSOCIATES
6802 Paragon Place, Suite 410
Richmond, Virginia 23230
(804) 426-5645 (telephone)
(804) 441-6001 (facsimile)
Email: jerroldmyronsmith@msn.com
Counsel for Plaintiff Monica Ball

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 27th day of July, 2013, a copy of the foregoing was sent by electronic mail to:

Damon W.D. Wright, Va. Bar No. 40319
Stephen H. Swart, Va. Bar No. 79125
VENABLE LLP
8010 Towers Crescent Drive, Suite 300
Tysons Corner, Virginia 22182
202-344-4937 (telephone) 202-344-8300 (facsimile)
dwdwright@venable.com
shswart@venable.com

Counsel for Defendants Takeda Pharmaceuticals America, Inc. and Takeda Pharmaceutical Company, Ltd.

/s/Jerrod M. Smith (VSB #66279)
JERROD MYRON SMITH & ASSOCIATES
6802 Paragon Place, Suite 410
Richmond, Virginia 23230
(804) 426-5645 (telephone)
(804) 441-6001 (facsimile)
Email: jerrodmyronsmith@msn.com
Counsel for Plaintiff